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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/738,742	12/15/2000	Jason Hill	CUB-4 US	2149

34103 7590 08/08/2003

CUBIST PHARMACEUTICALS, INC.
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LEXINGTON, MA 02421

EXAMINER

LUKTON, DAVID

ART UNIT

PAPER NUMBER

1653

DATE MAILED: 08/08/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/738,742

Applicant(s)

HILL ET AL.

Examiner

David Lukton

Art Unit

1653

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-12,15-27 and 30-36 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,16-26,30 and 36 is/are rejected.
- 7) ☒ Claim(s) 5-12,27 and 31-35 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Pursuant to the directives of paper No. 14 (filed 5/28/03), claims 5-7 and 23 have been amended, and claims 33-36 added. Claims 1, 2, 5-12, 15-27, 30-36 are pending. Claims 16-26 and 30 are rejoined with the elected group. Claims 1, 2, 5-12, 15-27, 30-36 are examined in this Office action.

*

Claims 1 and 2 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claim 1 of copending application Serial No. 09/739,535. Although the conflicting claims are not identical, they are not patentably distinct from each other. There is overlap of the claimed genera. Applicants have not traversed this ground of rejection, and so it is maintained without further comment.

[This is a *provisional* obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

The obviousness-type double patenting rejection is a judicially established doctrine based upon public policy and is primarily intended to prevent prolongation of the patent term by prohibiting claims in a second patent not patentably distinct from claims in a first patent. In re Vogel, 164 USPQ 619 (CCPA 1970). A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) would overcome an actual or provisional rejection on this ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d)

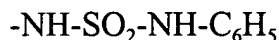
*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

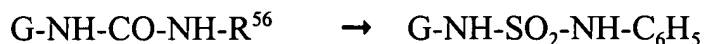
The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 30 is rejected under 35 U.S.C. §112, first paragraph, for the reasons set forth in the objection to the specification.

Claim 30 is drawn to a method of converting a compound of claim 27 into a compound of claim 1 or 2. However, the specification does not explain how to do this. Suppose, for example, that the "target" compound is one falling within the scope of claim 1 wherein the ring (containing variables K and K') is an imidazole group. How would one go about deleting the aniline group of claim 27 and replacing it with an imidazole group? Or suppose that variable "R" in claim 1 represented the following:



Letting "G" represent the remainder of the molecule, the required transformation would then be the following:



Regardless of what R^{56} might be, it is difficult to see how such a transformation would be undertaken. Applicants are requested to point to the relevant page and line number.

Perhaps what is intended is that the compounds of claim 27 can be used to prepare a compound falling within a narrow subgenus of claim 1 or 2. If this is intended (and new matter can be avoided), perhaps one option would be to identify such a subgenus.

*

The following is a quotation of the first paragraph of 35 U.S.C. §112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it in such full, clear, concise and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 16-26 and 36 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Claim 16 is drawn to each of two separate methods. The first is a method of "treating" a bacterial infection. The second is that of "preventing" a bacterial infection. This ground of rejection is directed at the second of these two methods. It may be the case that a patient stricken with a bacterial infection can derive benefit from the claimed compounds. However, "prevention" is another matter. This term implies that in 100% of cases, no sign of any infection can be detected, regardless of the circumstances. For example, suppose that one of the claimed compounds were administered to each of 10,000 persons, and that subsequently, each of those persons were subjected to an (otherwise) lethal dose of anthrax. Needless to say, it would not be easy to find volunteers for such a study, but the point is that if just one of those 10,000 persons were to develop symptoms of a bacterial infection, however minor, such a result would actually constitute evidence that prevention

had not been achieved. It is suggested that the ter "preventing" be deleted from the claims.

*

Claims 16-26, 30, 36 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 16 is indefinite as to the process steps and endpoint. One option for claim language would be the following:

A method of treating a bacterial infection ... comprising the step of administering ... the pharmaceutical composition... to a subject in need thereof *for a time and under conditions effective to ameliorate said bacterial infection.*

- In claim 24, the various trademark terms may be used, if accompanied by the chemical terms that these names represent.
- Claim 30 is indefinite as to the process steps. Suppose, for example, that the "target" compound is one falling within the scope of claim 1 wherein the ring (containing variables K and K') is an imidazole group. How would one go about deleting the aniline group of claim 27 and replacing it with an imidazole group?

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Serial No. 09/738,742
Art Unit 1653

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 703-308-3213. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. The fax number for the organization where this application or proceeding is assigned is 703-872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.



**DAVID LUKTON
PATENT EXAMINER
GROUP 120**